Design Controls

FDA Small Business
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Outline

- **Introduction to design controls**
- **Requirements for design controls**
  - Design planning
  - Design input and output
  - Design verification and validation
  - Design review
  - Design changes
  - Design transfer
  - Design history file
- **Resources and FDA contact**

Introduction

- Quality System (QS) Regulation: 21CFR 820
  - Management controls
  - Design controls
  - Production and process controls
  - Corrective and preventive actions

- Design controls are a part of QS Regulation

Introduction

- **44%** of …voluntary recalls from 1983 to 1989 …may have been prevented by adequate design controls.

  Source: ‘‘Device Recalls: A Study of Quality Problems’’ (see 55 FR 21108, May 22, 1990)

- **90%** of all software related device failures were due to design related error.

  Source: “FDA Medical Device Regulation from Premarket Review to Recall” (FDA/HHS OEI 09-90-0040, February 1991)

Introduction

- Safe Medical Device Act of 1990 authorized FDA to add design controls to the cGMP requirements for devices.
- The QS Regulation with design controls became effective on June 1, 1997, replacing the 1978 GMP for medical devices.
- Preamble to the QS regulation: very important

Design Controls - Purpose

- To control the design process to assure that devices meet:

  -User needs
  -Intended uses
  -Specified requirements

Design Controls – Scope

- Design controls apply to:
  - All **Class II** and **Class III** devices
  - The following **Class I** devices:
    - Devices automated with computer software
    - Tracheobronchial suction catheters
    - Surgeon's gloves
    - Protective restraints
    - Manual radionuclide applicator system
    - Radionuclide teletherapy source

Design Control Requirements

- General requirements
- Design and development planning
- Design input
- Design output
- Design verification
- Design validation
- Design review
- Design changes
- Design transfer
- Design history file

General Requirements

21CFR 820.30(a)

Design Controls – General

- Establish and maintain procedures to control the design of the device

- Establish means define, document and implement

Design and Development Planning

21CFR 820.30(b)

Design & Development Planning

- Establish and maintain plans that:
  - Describe or reference design and development activities
  - Define **responsibility** for implementation
  - Identify or describe **interfaces** with different groups or activities
  - Review, document, update and approve plans as design and development evolves

Design Input

21CFR 820.30(c)

Definition

- ***Design input*** means the physical and performance requirements of a device that are used as a basis for device design.

Design Input

- Establish and maintain procedures for design input
  - Ensure requirements are appropriate and address intended use of device
  - Address incomplete, ambiguous, or conflicting requirements
  - Document, review, and approve input requirements

Sources of Design Input

- MDRs
- Complaints
- Service reports
- CAPA
- Customers
- Focus groups
- Competitors' products
- Standards
- Marketing surveys
- Sales feedback

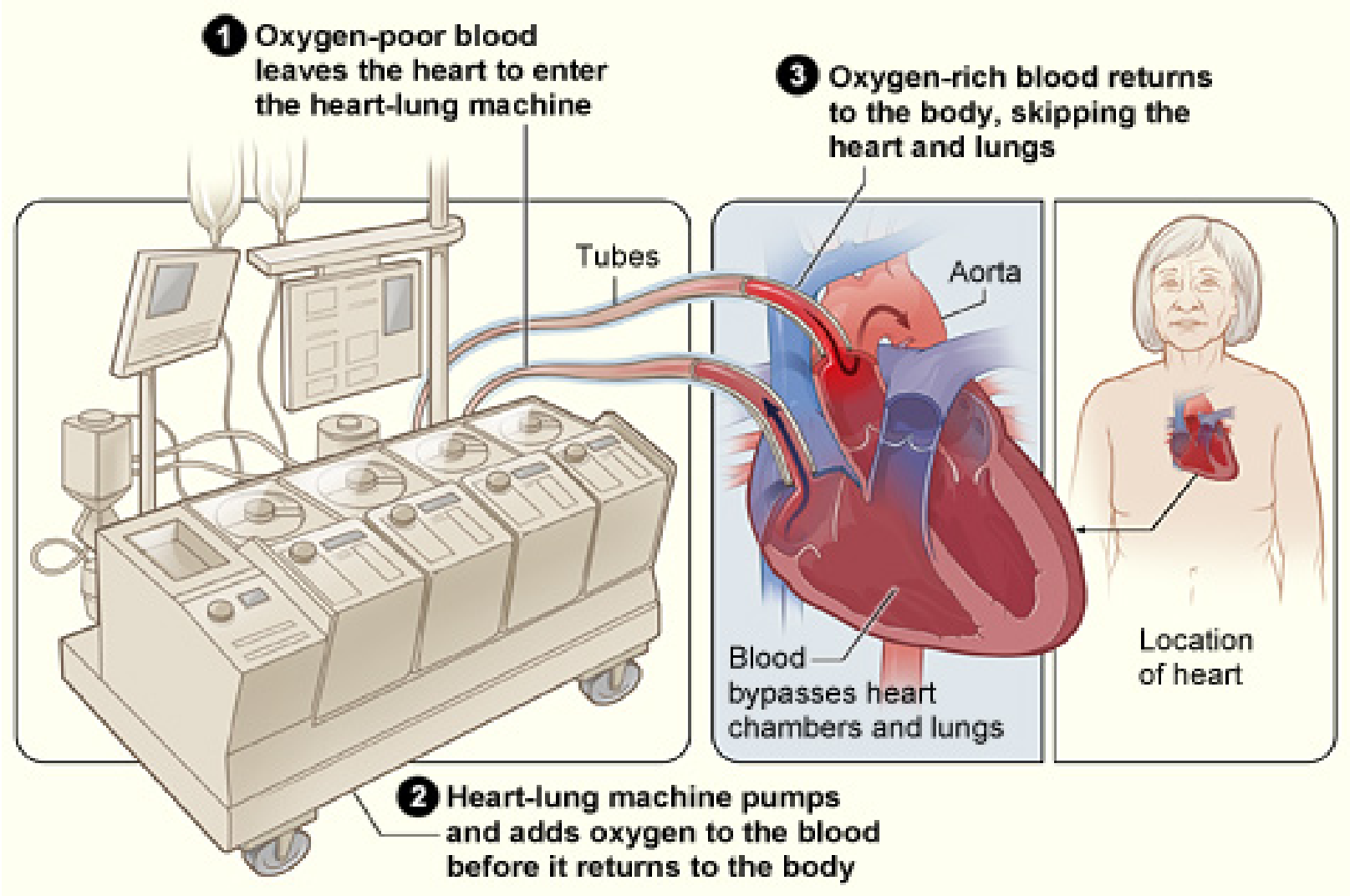
Types of Design Input

- Device functions
- Physical characteristics
- Performance
- Safety
- Reliability
- Environmental limits
- Sterilization
- Standards
- Regulatory requirements
- Labeling & packaging
- Human factors
- Maintenance
- Compatibility with other devices

Recall

Example: Cardiovascular Bypass Pump

- Pump stops when surgeons use electrocautery units in the operating rooms.


1 Oxygen-poor blood leaves the heart to enter the heart-lung machine
3 Oxygen-rich blood returns to the body, skipping the heart and lungs
Tubes
Aorta
Blood bypasses heart chambers and lungs
Location of heart
2 Heart-lung machine pumps and adds oxygen to the blood before it returns to the body

Questions

- What are the user needs?
- What kinds of design input are needed to avoid this problem?
- In what environment is the blood pump supposed to function?
- What kinds of equipment will it be used with?

Design Input

User Need

Pump must function in an operating room environment.

Design Input (Abbr.)

Pump must function uninterrupted when used with electrocautery equipment and external defibrillators.

Design Output

21CFR 820.30(d)

Definition

- ***Design output*** means the results of a design effort at each design phase and at the end of the total design effort.

The total finished design output consists of the device, its packaging and labeling, and the device master record.

In other words...

- "***Design output*** are the design specifications which must meet design input requirements, as confirmed during design verification and validation and ensured during design review.

Design Output

User Need

Pump must function in an operating room environment.

Design Input (abbr.)

Pump must function uninterrupted when used with electrocautery equipment and external defibrillators.

Design Output (abbr.)

- PCB with filtering circuit
- Pump EMI shield
- Software signal filtering code and error handling code

Design Output

- Establish and maintain procedures for design output
  - Establish and maintain procedures for defining and documenting design output ***in terms that allow an adequate evaluation of conformance to design input***
  - Reference ***acceptance criteria***
  - Identify design outputs that are essential for the proper functioning of the device
  - Review and approve design output before release

Design Output

- Design Outputs are included in premarket submissions as device specifications.

Design Verification

21CFR 820.30(f)

Definition

- ***Verification*** means confirmation by examination and provision of objective evidence that specified requirements have been fulfilled

Design Verification

- Establish and maintain procedures for verifying the device design
- Confirm design output meets design input requirements
- Review, approve and document in design history file

Design Verification

User Need

Pump must function in an operating room environment.

Design Input (abbr.)

Pump must function uninterrupted when used with electrocautery equipment and defibrillators.

Design Output (abbr.)

- PCB with filtering circuit
- Pump EMI shield
- Software signal filtering code and error handling code

Design Verification (abbr.)

- Simulated EMI testing on hardware and software
- Dimensional verification of shield
- Verification of system error handling due to EMI

Design Verification

- Many test reports associated with Design Verification are included in premarket submissions:
  - 510(k)s
  - Premarket Approval Applications (PMAs)
  - Investigational Device Exemptions (IDEs)

Design Validation

21CFR 820.30(g)

Definition

- ***Design validation*** means establishing by objective evidence that device specifications conform with user needs and intended use(s)

Design Validation

- Establish and maintain procedures for validating the device design

- Perform design validation
  - Under defined operating conditions
  - On initial production units, lots or batches or their equivalents
  - Under actual or simulated use conditions

Design Validation

- Ensure that devices conform to defined user needs and intended uses

- Perform software validation and risk analysis, where appropriate

Verification vs. Validation

- **Design Verification**
  - Design output meets design input
  - “Did I make the product right?”
- **Design Validation**
  - Design output meets user needs and intended use(s)
  - “Did I make the right product?”

User Need

Pump must function in an operating room environment.

Design Input (abbr.)

Pump must function uninterrupted when used with electrocautery equipment and external defibrillators.

Design Outputs: (abbr.)

- PCB with filtering circuit
- Pump EMI shield
- Software signal filtering code and error handling code

Design Verification (abbr.)

- Simulated EMI testing on hardware and software
- Dimensional verification of shield
- Verification of system error handling due to EMI

Design Validation (abbr.)

- EMC testing to industry standards
- Simulated EMI testing in OR
- Risk Analysis concerning EMI
- Software validation for filtering code

Warning Letter Example

Failure to establish and maintain adequate procedures for validating the device design and risk analysis, where appropriate, as required by 21 CFR 820.30(g).

For example: The design files for XXX did not include documentation the device had ever been validated before production and marketing. When requested, your firm was unable to provide documentation validation had been performed.

Design Validation

- The results of Design Validation are typically submitted in premarket submissions

- **Examples:**
  - Animal study protocols/reports
  - Cadaver study protocols/reports
  - Clinical study protocols/reports

Design Review

21CFR 820.30(e)

Design Review

- ***Design Review*** means a documented, comprehensive, systematic examination to:
  - Evaluate adequacy of the design requirements
  - Evaluate capability of the design to meet requirements
  - Identify any problems

Design Review

- Establish and maintain procedures for design reviews
- Plan and conduct formal documented ***design reviews*** of the design results at appropriate stages

Design Review

- Include at each design review
  - Representatives of all functions concerned
  - An individual without **direct responsibility** for the stage being reviewed
  - Any specialists needed

Design Review

- Document results of design review in Design History File, including:
  - Identification of design
  - Date
  - Individuals performing review

Design Changes

21CFR 820.30(i)

Design Changes

- Establish and maintain procedures for the identification, documentation, ***validation*** or ***where appropriate verification***, review, and approval of design changes before their implementation

Device Recall: Portable Ventilator

- **Reason:** The Universal Cable Adaptor intended to correct an earlier Class I recall is not functioning as intended. The adaptor may not allow the ventilator to be powered up again if the ventilator's internal battery has been depleted or may not be securely attached to the pigtail connector on the ventilator.
- **Distribution:** 10,299 units. Nationwide and Internationally.
- **Classification:** Class II, following an earlier Class I

Design Changes

- Depending on the scope and impact of the change, the change may require:
  - A new 510(k)
  - A new PMA, a PMA supplement, or a PMA 30-Day Notice
  - A new IDE or an IDE supplement
- Changes must be communicated with FDA if the device is under premarket review or IDE review

Design Transfer

21CFR 812.30(h)

Design Transfer

- Establish and maintain procedures to ensure that the device design is correctly translated into production

Design Transfer

- Although transfer happens throughout, there frequently is a final stage of development intended to ensure all outputs are adequately transferred to manufacturing (and suppliers).

Design History File

21CFR 820.30(j)

Definition

- ***Design history file (DHF)*** means a compilation of records which describes the design history of a finished device

Design History File

- Establish and maintain a design history file for each type of device
- Include in the DHF or reference records information necessary to demonstrate that the design was developed in accordance with the **design plan** and 21CFR 820 requirements

Resources

- **CDRH Learn**

  Online video training modules that include premarket and post-market topics
  http://www.fda.gov/Training/CDRHLearn/ucm162015.htm

- **Device Advice**

  Self-service website searchable by topics
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

QS Regulation and Guidance

- **Quality System Regulation and Preamble**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/ucm230127.htm

- **Medical Device Quality Systems Manual: A Small Entity Compliance Guide**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/MedicalDeviceQualitySystemsManual/default.htm

- **Design Control Guidance For Medical Device Manufacturers**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070627.htm

- **Do it By Design – An Introduction to Human Factors in Medical Devices**
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095061.pdf

- **Guidance for Industry and FDA Premarket and Design Control Reviewers – Medical Device Use – Safety: Incorporating Human Factors Engineering into Risk Management**
  http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM094461.pdf

QS Regulation and Guidance

- **Guidance for Industry: Part 11, Electronic Records; Electronic Signatures - Scope and Application**
  http://www.fda.gov/RegulatoryInformation/Guidances/ucm125067.htm

- **General Principles of Software Validation**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085281.htm

- **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm

- **Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices**
  http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073778.htm

Need Assistance?

Division of Small Manufacturers, International and Consumer Assistance (DSMICA)

- **Email:** dsmica@fda.hhs.gov
- **Phone:** 301-796-7100 or 800-638-2041